

Remarks

Example 1 of the specification is amended to remove the erroneous statement that acetone is added to a liquid and is replaced with the correct statement that acetone is added to the insoluble material. Support for this amendment can be found, *inter alia*, on page 7 in paragraph [0021].

Claims 1-20 remain in this application. Claim 4 is amended to remove indefiniteness. Support for this amendment can be found on page 6 in paragraph [0020].

The Instant Invention – An Overview

Claim 1 is drawn to a method of making a Bowman-Birk Inhibitor concentrate, comprising the steps of:

- (A) providing acid extracted solubles from a defatted soybean material;
- (B) mixing acetone with the acid extracted solubles to form a precipitate;
- (C) separating the precipitate from the mixture of acetone and acid extracted solubles;
- (D) diluting the separated precipitate with water to form an aqueous solution; and
- (E) ultrafiltering the aqueous solution to obtain a retentate.

In step (A), acid extracted solubles are obtained from a defatted soybean material. In claim 5, the defatted material comprises defatted soybean flakes or defatted soybean flour. In claim 6, the defatted soybean flakes are mixed with water to form a slurry. In claim 7, the pH of the slurry is adjusted to 4.0 to 6.5 using hydrochloric acid. This step forms soy protein precipitate and a liquor. The protein precipitate and liquor are separated in claim 9. It is the liquor that is the acid extracted solubles.

Acetone is added to the acid extracted solubles which causes a Bowman-Birk Inhibitor (BBI) precipitate to form (claim 1 step (B)). In claim 1 step (C), the BBI precipitate is separated. In claim 1, step (D) water is added to the separated precipitate to form an aqueous dispersion and the aqueous dispersion is subjected to ultrafiltration to generate a retentate, which is the BBI concentrate, claim 1 step (E).

It is important to note that in the present invention, acetone is added before ultrafiltration.

**I. Rejection Under 35 §USC 112**

Claim 4 is rejected under 35 §USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

It is pointed out within the Office Action that the antecedent basis for "the precipitate" in claim 4 is unclear since there are two precipitates formed in claim 1. Applicants have amended claim 4 such that "the precipitate" of claim 4 is defined as being the separated precipitate of the mixture of acetone and acid extracted solubles. Reconsideration and withdrawal of this rejection is respectfully requested.

**II. Rejection Under 35 §USC 102 (b)**

Claims 1, 3, 5-7, 10 and 14-16 are rejected under 35 §USC 102(b) as being anticipated by US Pat. No. 5,505,946 ('946).

A total of 5 embodiments are outlined in '946 beginning at col. 4, line 46 to col. 5, line 35. In the first 4 embodiments it is necessary to generate either a crude BBI concentrate (CBBIC) or a semi-crude BBI concentrate (SCBBIC). The CBBIC or SCBBIC are prepared from hexane defatted soybeans wherein the soy protein is aqueous extracted from the hexane defatted soybeans. Added to the protein extract is an acid that generates a slurry of a soy protein precipitate as a curd. The remaining phase is a liquor that is defined as the acid extracted solubles. Water is added to the slurry and the contents are centrifuged to solids and a centrate. The centrate is the purified soybean solubles. Additional water is added to make a reslurried soybean solubles which when ultrafiltered gives a CBBIC. When the ultrafiltered step is repeated, a SCBBIC is obtained.

In the first embodiment of '946 beginning at col. 4, line 60, added to either the CBBIC or SCBBIC is acetone to produce a BBI precipitate. After settling and decanting, the precipitate is dried, reslurried, filtered and lyophilized to produce a BBI concentrate.

In the second embodiment of '946 beginning at col. 4, line 66, added to SCBBIC is acetone to produce a BBI precipitate. The BBI precipitate is worked up as per the first embodiment with the exception that the filtered precipitate is spray dried rather than lyophilized.

In embodiments three and four of '946, BBI Concentrate is prepared from CBBIC without the use of acetone.

In the fifth embodiment of '946, beginning at col. 5, line 22, acid extracted soybean solubles are centrifuged to prepare a purified soybean solubles supernatant. Acetone is added to the supernatant to precipitate a CBBIC. The precipitate is resuspended in water and centrifuged. Again acetone is added to the second supernatant to again precipitate BBI. The precipitate is dried to produce a BBI product. This embodiment does not employ ultrafiltration.

The present invention does not read on any of the five embodiments of '946. The present invention produces BBI by employing the acetone precipitate step before the ultrafiltration step. In '946, BBI is produced by employing the ultrafiltration before the acetone precipitate step (when ultrafiltration and acetone are both employed).

In the Office Action, Example 1 of '946 is compared such that the Example 1 corresponds to steps A through E of the present invention. This comparison is erroneous. In Example 1, hexane extracted soy flour is mixed with a 60% ethanol solution. This generates a slurry of protein precipitate and a liquor. The liquor is alcohol extracted solubles. Hydrochloric acid is added to the alcohol extracted solubles followed by the addition of acetone which produces a BBI precipitate. The use of an acid with the acetone promotes BBI precipitate. It is important to note that Example 1 does not employ acid extracted solubles, but rather alcohol extracted solubles. Adding acid to alcohol extracted solubles does not generate acid extracted solubles. The present invention is not anticipated by Example 1 of '946 or by any of the five embodiments of '946. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

## **II. Rejection Under 35 §USC 103 (a)**

Claims 1, 2, 4-13 and 16-20 are rejected under 35 §USC 103 (a) as obvious over US Patent No. 5,505,946 ('946).

For the reasons discuss above, Example 1 of '946 does not meet the largest majority of the present invention simply because Example 1 employs as a first step alcohol extracted solubles and the present invention employs in step A, acid extracted solubles. While it is true that both Example 1 of '946 and Example 1 of the present invention generate BBI, the

chymotrypsin inhibitor level of Example 1 of '946 is 70.4 mg/g and the chymotrypsin inhibitor level of Example 1 of the present invention is 252.7. The only difference between Example 1 of '946 and Example 1 of the present invention is in alcohol extracted solubles ('946) and acid extracted solubles (present invention).

The remaining comparisons of Example 1 of '946 to the present invention are rendered moot due to the use of the alcohol extracted solubles of '946 and not the acid extracted solubles of the present invention. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

Claims 1-20 are provisionally rejected under 35 §USC 103 (a) as obvious over copending Application No. 10/197,297 ('297) in view of US Patent No. 5,505,946 ('946).

For purposes of discussion, a centrate as used herein below, is prepared from acid extracted soybean solubles that are centrifuged.

The '297 prepares a BBI product by adding acetone to the centrate to form a BBI precipitate. The liquid phase is separated and discarded. Acetone is added to the remaining precipitate to form a BBI slurry. Again the liquid phase is separated and discarded. The wet precipitate is filtered and air dried. Water is added to the air dried product followed by filtration and the filtrate is spray dried to give a BBI product having a chymotrypsin inhibitor level of 103 mg/g in Example 1 and 146 mg/g in Example 2. No ultrafiltration is employed in '297.

In embodiments one and two of '946, a BBI product is prepared by subjecting the centrate to ultrafiltration followed by the addition of acetone to the ultrafiltrate. A BBI precipitate slurry is formed. The liquid phase is separated and discarded. The wet precipitate is filtered and air dried. Water is added to the air dried product followed by filtration and the filtrate is spray dried to give a BBI product having a chymotrypsin inhibitor level of 135.5 mg/g in Example 1 and 261 mg/g in Example 2. Ultrafiltration is employed before the addition of acetone.

In the fifth embodiment of '946, acetone is added to the centrate to form a BBI precipitate. The liquid phase is separated and discarded. Acetone is added to the remaining precipitate to form a BBI slurry. Again the liquid phase is separated and discarded. The wet precipitate is filtered and air dried. No ultrafiltration is employed.

As discuss above, Example 1 of '946 does not use acid extracted solubles for the preparation of the BBI product.

In the present invention, acetone is added to the centrate to form a BBI precipitate. The liquid phase is separated and discarded. Acetone is added to the remaining precipitate to form a BBI slurry. Again the liquid phase is separated and discarded. The wet precipitate is filtered and air dried. Water is added to the air dried product to form a dispersion followed by filtration and the filtrate is subjected to ultrafiltration followed by spray drying to give a BBI product having a chymotrypsin inhibitor level of 252 mg/g in Example 1 and 391 mg/g in Example 2.

Combining the teachings of '297 with '946, as urged in the Office Action, does not render the present invention as obvious. The '297 employs two acetone steps to give a BBI product having a chymotrypsin inhibitor level of at most 146 mg/g. The '946 employs ultrafiltration to give a BBI product having a chymotrypsin inhibitor level of at most 261 mg/g. The present invention employs both two acetone steps and ultrafiltration to give a BBI product having a chymotrypsin inhibitor level of at most 391 mg/g. Proof of unobviousness of a claimed process can be evidence of unexpectedly superior physical or chemical properties of the product thereof, commercial success, solution of longfelt need, prior art teaching away from the invention, less expensive operation, etc. *In re Muchmore* (CCPA 1970) 433 F2d 824, 167 USPQ 681. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

#### Double Patenting

Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/197,297 in view of US Patent No. 5,505,946. Submitted with this amendment is a terminal disclaimer to overcome the double patenting rejection. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims are earnestly solicited.

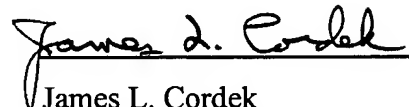
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If any additional fees are due in connection with the filing of this document, the Commissioner is authorized to charge those fees to our Deposit Account No. 50-0421.

Respectfully submitted,  
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